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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,282	11/19/2003	Scott R. Presnell	00-49C1	8902

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,282

Applicant(s)

PRESNELL ET AL.

Examiner

Fozia M. Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: _____ |

Response to Amendment

1a. Receipt of Applicants' amendment and arguments, filed on 22 May 2006 is acknowledged.

Status of Claims:

1b. Claim 1-14 are pending and under consideration.

Specification:

2. It is noted that the title has been changed.

Response to Applicants' arguments:

3. The following previous objections and rejections are withdrawn in light of Applicants amendment filed 05/22/2006:

(I) The rejection against claims 2-3 made under 35 U.S.C. 112, second is withdrawn. It is now clear that the encoded polypeptide comprises the amino acid sequence set forth in SEQ ID NO:2.

Claim Rejections - 35 U.S.C. § 101/112:

4a. The rejection of claims 1-14 made under 35 U.S.C. § 101 and §112, first paragraph, is maintained for reasons of record set forth in the office action mailed on 21 February 2006. The instant claims 1-14 are drawn to an isolated nucleic acid (SEQ ID NO:1) encoding the polypeptide of SEQ ID NO:2, an expression vector comprising said nucleic acid, a recombinant host cell comprising said vector and a method of expressing the encoded polypeptide.

Applicant argues that the Examiner has not made a prima case for holding lack of utility and failed to provide any evidence or sound scientific reasoning to refute the

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asserted utility. Applicant submits that upon reading the specification, one of skill in the art would appreciate that zctyoRI8 is a member of the sufficiently conserved interleukin-17 related receptor family of proteins and would reasonably impute that same specific, substantial and credible utility to ZctyoRI8. Thus, Applicant concludes that the invention of claims 1-14 is useful.

This argument has been fully considered, but is not deemed persuasive.

Applicant does not disclose which IL-17 ligand does the receptor encoded by the claimed nucleic acid, bind to, and what biological activity is regulated after said binding. Contrary to Applicant's argument, the interleukin 17 receptor family is a newly emerging family that share partial sequence homology. To date, five IL-17 receptors have been identified, IL-17R, IL-17A, IL-17B, IL-17D (also known as sef or IL-17RLM) and IL-17E. Moseley et al (Cytokine and Growth Factor Reviews, Vol. 14, No.2, 2003, pages 155-174), teach that the members of this receptor family exhibit a broad tissue distribution and that much is not known about their functions, (see page 156, top of column 2). The claimed polypeptide shares 97.6% homology with IL-17RD (sef), however, the claimed polypeptide has an extra 14 amino acid residues at amino acid residues 43-56, and there are also other differences between the two sequences (see attached sequence comparison A). The instant specification does not teach that the polypeptide encoded by the claimed nucleic acid binds to any of the IL-17 ligands, therefore, just because it shares some homology to this newly emerging family, does not impart function for it. As discussed in *Brenner v. Manson*, (1966, 383 U.S. 519, 148 USPQ 689), the court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and, “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion.”

Accordingly, Applicant's assertion that the polypeptide of the instant invention, would have utility because of its homology to IL-17 receptor family of proteins is not substantial.

Furthermore, it is known that even a single amino acid change or mutation in a protein can destroy the function of the protein in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the argument that the claimed polypeptide shares sequence homology with IL-17 receptors results in an unpredictable and therefore unreliable correspondence between the claimed polypeptide and the indicated known function and therefore lacks support regarding enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over proteins of related function upon a significant amount of further research (see Wells, 1990, Biochemistry 29:8509-8517). Further research would have to be conducted to determine the biological significance of the polypeptide of SEQ ID NO:2, encoded by the claimed nucleic acid, however, this further research is part of the act of the invention, and unless it has been undertaken, the invention is incomplete.

Conclusion:

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5. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
07 August 2006


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